March 31, 2005

Delivered by electronic mail

Gary M. Jackson
Assistant Administrator For Size Standards
Office of Size Standards
Small Business Administration
409 Third Street, SW
Washington, DC 20416

Re: <u>Proposed Rulemaking Affecting SBIR Funding</u>

Dear Mr. Jackson:

Alexza Molecular Delivery Corporation ("Alexza") is a Palo Alto, California based life science company formed in December 2000. We are developing unique pulmonary delivery technology for the rapid, non-invasive administration of therapeutics, and we currently employ 85 people, most of whom are scientists or engineers. We have been fortunate to have received SBIR funding on eight separate grants. We have used the funds to support research on the application of our delivery technology to therapeutic areas of significant medical interest.

The SBIR grants have been an important source of support for Alexza, however, we have also raised over $100 million of equity capital in four separate rounds of private financing. Although we have a number of individual stockholders, by far the largest source of investment capital for life science firms such as Alexza is the venture capital industry, and after four rounds of financing an aggregate of more than 51% of our outstanding capital stock is owned by over 10 venture capital funds.

As a result of the rule issued by the SBA on December 3, 2004, requiring that an SBIR award recipient must be at least 51% owned and controlled by one or more **individuals** who are U.S. citizens (the "51% Rule"), we are no longer eligible for SBIR funding. We believe this is an unfortunate result for the SBIR program, for Alexza, for similarly situated life science companies in the United States and for the economy and technological development of the United States. **We believe that the SBA should provide an exception to the 51% Rule to include venture capital firms in the definition of "individuals."**

Background

The SBIR program was created by the Small Business Innovation Development Act of 1982 ("SBIDA"). The purposes of SBIDA, as set forth in the statute, are to stimulate technological innovation, to use small business to meet Federal research and development needs, to foster and encourage participation by minority and disadvantaged persons in technological innovation, and to increase private sector commercialization of innovations derived from Federally funded research and development. By all accounts this program has been highly successful. A large number of grants have been awarded to a broad range of small business concerns during the last 23 years, and this funding has supported the development of various important technologies. Until very recently, the SBIR grants were awarded to small businesses without concern as to their funding sources, as long as the recipients were more than 51% owned by United States citizens. This can be confirmed by a review of the grant recipients during the period from 1993 to 1998 which is available on the web page of the SBA SBIR/STTR: www.sba.gov/sbir/indexsbir-sttr.html. Many of the recipients were owned more than 51% by venture capital firms, and some recipients were publicly held. Since most of the stockholdings of public companies are held in "street name," presumably publicly held recipients could not determine whether their shares were held 51% by individuals who are U.S. citizens.

Funding Requirements of Life Science Companies

Life science companies in the United States today are innovators in the development of life saving technology and have been responsible for the development of numerous breakthrough therapeutic and diagnostic products and medical devices in fields such as cancer, cardiovascular disease and central nervous system disorders. In addition, they have created a substantial number of high paying, skilled jobs throughout the United States. These companies are required to raise huge amounts of funding to develop and commercialize products in the highly regulated device and therapeutic markets. In the vast majority of cases, the only way to raise the necessary sums of capital is to resort to venture capital investors. As mentioned above, Alexza has raised a significant amount of private funding from venture capital firms, and in this regard we are similar to hundreds of privately held life science companies in the San Francisco Bay Area, San Diego, Seattle, Cambridge, Philadelphia, New Jersey and many other areas in the United States. Since many of these venture capital backed life science companies have top scientists conducting ground breaking research, it is critical to the United States economy that venture investment and SBIR funding not be mutually exclusive but work in a symbiotic fashion to promote the goals of SBIDA. If the SBA makes companies that are 51% or more owned by venture capital investors ineligible for SBA grants, the vast majority of the most capable life science companies in the United States will be ineligible. This cannot be a desirable result from the point of view of the SBA or United States public policy.

Structure of Venture Capital Funds

We understand the 51% Rule now allows an SBIR award recipient to be owned by a venture capital fund, as long as the venture capital fund is itself owned and controlled by U.S. individuals. Venture capital funds are commonly structured as limited partnerships or limited liability companies and the investors in venture capital funds are generally comprised of private and public pension funds, financial and insurance investors, endowments and foundations, individuals and families. Due to the non-individual nature of most of these investors, however, most venture capital portfolio companies cease to be eligible for SBIR funding, even under the 51% Rule.

Venture Capital Funds Should Be Considered Individuals in Determining SBIR Eligibility

We believe that the SBIR eligibility requirements should not differentiate between natural persons and other legally recognized entities with respect to venture capital funds. There is no statutory or legislative support, including the SBA's own legislative history, for the regulations which limit eligible awardees under the 51% Rule to those owned by "individuals". Congressional intent in passing SBIDA was to increase the amount of Federal research and development support for highly innovative small businesses, bolstering the competitive position of the United States. Therefore the current interpretation of the 51% Rule is inconsistent with SBIDA. Instead, the effect of the 51% Rule will be to continue to prevent many small businesses that have received venture financing from receiving SBIR financing, and vice versa, thereby undermining competitiveness and job creation in many areas that have active life science companies, such as the San Francisco Bay Area and San Diego.

We suggest that the SBA propose a rule that the term "individuals" in the current regulations be defined to include both natural persons and venture capital firms, in addition to other types of entities the SBA may decide should be similarly included, e.g., employee benefit or pension plans, non-profit organizations, etc. By doing so, the SBA will ensure that SBIR funded companies will have the resources to ensure the commercialization of the funded research. Such a modification would permit small businesses which are funded by venture capital funds to be eligible to receive SBIR award and would help to further the Congressional goals of establishing the SBIR program.

By re-opening the SBIR program to companies which are venture financed, the SBIR program will attract a broad base of applicants, ensuring that the most innovative technologies with the most scientific merit and commercial feasibility will be allowed to compete for grant awards. Otherwise, by limiting the program to non-venture financed companies, the pool of applicants will be smaller; many innovative technologies will be overlooked, as they may be ineligible to apply for grants.

We respectfully request that the SBA provide an exception to the 51% Rule to include venture capital funds in the definition of "individuals."

Thank you for providing us an opportunity to comment on this matter.

Very truly yours,
Alexza Molecular Delivery Corporation

By:_____________________
August J. Moretti
Chief Financial Officer

cc: Hon. Dianne Feinstein
Hon. Barbara Boxer
Hon. Anna Eshoo